

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

DEREK GUBALA and JOHN NORRIS,)	
individually and on behalf of all others)	
similarly situated,)	
)	
Plaintiffs,)	
)	No. 14 C 9299
v.)	
)	Judge Sara L. Ellis
HBS INTERNATIONAL CORP.,)	
a Canadian Corporation,)	
)	
Defendant.)	

OPINION AND ORDER

Believing that Defendant HBS International Corporation (“HBS”) has mislabeled its protein supplement HexaPro (“HexaPro”) by (a) boasting a protein content and daily value of protein per serving calculated with the wrong methodology, (b) falsely claiming HexaPro includes Branched Chain Amino Acids (“BCAAs”), and (c) improperly adding other amino acids to HexaPro in violation of § 343(a) of the Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, as amended by the National Labeling and Education Act (“NLEA”), 21 U.S.C. § 341 *et seq.*, Plaintiffs Derek Gubala and John Norris (“Plaintiffs”) allege in their Second Amended Complaint (“SAC”)¹ that HBS is liable for violating the Illinois Consumer Fraud and Deceptive Business Practices Act (“ICFA”), 815 Ill. Comp. Stat. 505/1 *et seq.* and various other state consumer fraud acts, unjust enrichment, and breach of express warranty. HBS moves pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss Plaintiffs’ claims in their entirety

¹ The Court previously dismissed Plaintiffs’ First Amended Complaint because the Court found that the FDCA and NLEA preempted the claims and further, the claims failed as matter of law. Additionally the Court dismissed the FAC with respect to the parent company of HBS for lack of personal jurisdiction, and with respect to all claims related to the product “AllWhey” for lack of standing. Plaintiffs refiled their complaint to remedy the preemption issue and focused solely on HBS and HexaPro.

as preempted by the FDCA and NLEA and for failure to state a claim. Because Plaintiffs sufficiently allege that HBS violated the FDCA and NLEA with respect to the calculation of the protein content and the allegedly false addition of BCAAs, Plaintiffs' claims are not preempted and the Court denies HBS' motion. But Plaintiffs' claims with respect to the improper addition of the amino acids L-Taurine and L-Glycine are dismissed without prejudice because Plaintiffs do not allege a plausible set of facts that HBS' use of the amino acids violated the FDCA.

BACKGROUND²

HBS is a Canadian corporation selling bodybuilding and sports nutrition supplements, including HexaPro, in the United States and Canada through a variety of retailers. Gubala, an Illinois resident, and Norris, a South Carolina resident, both bought HexaPro at Vitamin Shoppe stores located in their respective states.

HexaPro's front label states in the upper right-hand corner that it contains "25 G[rams] Protein Per Serving." Plaintiffs allege this representation is misleading because HBS calculates the amount of protein using an impermissible method—the nitrogen content test—which counts "all of the nitrogen-containing, non-protein 'spiking' ingredients as actual protein." Doc. 52 ¶ 30. The process Plaintiffs refer to as "protein spiking," is one in which manufacturers add significant amounts of less expensive nitrogen-containing free-form amino acids to their product. Because FDA regulations generally permit protein content to be calculated based on the total nitrogen content of the product, manufacturers add these nitrogen containing amino acids to their product so that they can claim a higher protein content while keeping manufacturing costs low. Plaintiffs allege that the nitrogen test is not permissible in this circumstance and thus HBS

² The facts in the background section are taken from the SAC, and documents incorporated by reference therein, and are presumed true for the purpose of resolving HBS' motion to dismiss. *See Virnich v. Vorwald*, 664 F.3d 206, 212 (7th Cir. 2011); *Local 15, Int'l Bhd. of Elec. Workers, AFL-CIO v. Exelon Corp.*, 495 F.3d 779, 782 (7th Cir. 2007).

should use the more sensitive Protein Digestibility Corrected Amino Acid Score (“PDCAAS”) test³ because HBS makes a protein claim on HexaPro’s front label. If HBS calculates the protein content of HexaPro using the PDCAAS test, the added free-form amino acids would not be counted as protein. Plaintiffs further allege that HBS adds the free-form amino acids L-Glycine and L-Taurine solely to achieve higher nitrogen levels for purposes of protein spiking and that they do not improve the “biological quality of the total protein” in HexaPro in violation of 21 C.F.R. § 172.320. Doc. 52 ¶ 33.

HexaPro’s front label, back label, and list of ingredients also each state that HexaPro includes the BCAAs L-Leucine, L-Isoleucine, and L-Valine, which “provide positive health benefits and are sought after ingredients.” Doc. 52 ¶ 40. Plaintiffs allege that these BCAAs are not in fact included in HexaPro and thus the label is false and misleading.

LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) challenges the sufficiency of the complaint, not its merits. Fed. R. Civ. P. 12(b)(6); *Gibson v. City of Chicago*, 910 F.2d 1510, 1520 (7th Cir. 1990). In considering a Rule 12(b)(6) motion to dismiss, the Court accepts as true all well-pleaded facts in the complaint and draws all reasonable inferences from those facts in the plaintiff’s favor. *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011). To survive a Rule 12(b)(6) motion, the complaint must not only provide the defendant with fair notice of a claim’s basis but must also be facially plausible. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable

³ Plaintiffs describe the PDCAAS test as more a “sophisticated” test than the nitrogen test. Doc. 52 ¶ 25. PDCAAS distinguishes between actual protein and free-form amino acids and excludes such amino acids from the total protein count of a product.

for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. “While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitlement to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (internal citations omitted). “The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Iqbal*, 556 U.S. at 678.

ANALYSIS

Plaintiffs’ SAC aims to remedy the deficiencies of Plaintiffs’ prior two complaints primarily by proposing that HBS’ use of the nitrogen content test to determine protein content of HexaPro is improper, and that a more specific test—the PDCAAS test—is required. Plaintiffs also have added allegations that HBS has violated the FDCA by falsely claiming to add BCAAs and by adding other amino acids that do not improve the total biological content of the protein in HexaPro. HBS moves to dismiss Plaintiffs’ claims arguing they are preempted and fail to state a claim.

I. Preemption Defense

The FDCA does not provide a private right of action; therefore, Plaintiffs are only able to seek relief pursuant to related state-law causes of action. *See Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011). However, the FDCA expressly preempts state law claims that impose labeling requirements “not identical” to its own requirements. 21 U.S.C. § 343-1. For the purposes of preemption the FDA has said that:

“Not identical to”. . . means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that: (i) Are not imposed by or contained in the

applicable provision (including any implementing regulation) of section 401 or 403 of the act; or (ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act.

21 C.F.R. § 100.1(c)(4). Thus, a plaintiff must allege a violation of the FDCA to avoid preemption. *Trazo v. Nestle USA, Inc.*, NO. 5:12-CV-2272 PSG, 2013 WL 4083218, at *5 (N.D. Cal. Aug. 9, 2013) (“To avoid preemption under Section 343-1(a), the plaintiff must be suing for conduct that violates the FDCA.”).

HBS argues that Plaintiffs’ claims fail to allege violations of the FDCA and are preempted on three grounds: (1) the PDCAAS test is not required in this case because HexaPro’s label does not make a nutrient content claim; (2) even if the PDCAAS test is required, Plaintiffs’ failed to allege they conducted “12-sample” testing compliant with FDA regulations to support their protein content and BCAA claims; and (3) Plaintiffs’ allegations regarding the addition of L-Glycine and L-Taurine to HexaPro are bare, conclusory statements and thus fail to state a claim and are preempted. Doc. 54 at 2–3. The Court addresses each of these arguments in turn.

A. The PDCAAS Test is Required

HBS argues that it is not required to calculate the protein content of HexaPro using the PDCAAS test because that test is only required when the label of a product makes a protein content claim. Under 21 U.S.C. § 343(q), foods that are intended for human consumption must list certain nutritional information on their labels including “the total protein contained in each serving size or other unit or measure.” 21 U.S.C. § 343(q)(1)(D). FDA regulations allow “[p]rotein content [to] be calculated on the basis of the factor of 6.25 times the nitrogen content of the food.” 21 C.F.R. § 101.9(c)(7). 21 U.S.C. § 343(r) states, however, that if a food label makes a nutrient content claim about a nutrient, the statement must comply with additional specified requirements. *See also* 21 C.F.R. § 101.9(c)(7). A nutrient content claim is a “claim

that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.35.” 21 C.F.R. § 101.13(b). When such a claim is made about protein (a “protein claim”), then a statement of the corrected amount of protein per serving, not simply a nitrogen factor calculation, must be used. 21 C.F.R. § 101.9(c)(7)(i).

HBS first argues that the mere location of “25G Protein Per Serving” on the front label does not convert the statement into a nutrient content claim because the statement does not implicitly characterize the nutrient level of the food. However, as noted above, a nutrient content claim is one that either implicitly or *explicitly* characterizes the level of the nutrient in the product. 21 C.F.R. § 101.13(b). Section 101.13(b)(1) states that “[a]n expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., ‘low sodium’ or ‘contains 100 calories.’” 21 C.F.R. § 101.13(b)(1). Plaintiffs allege that the front-label statement “25G Protein Per Serving” is a direct statement about the level of protein in HexaPro and thus satisfies the requirements of § 101.13(b)(1).

HBS next argues that the front label statement should not be treated as a nutrient content claim because it simply restates information permissibly contained in the Supplemental Facts nutrition label. But § 101.13 states that information required by § 101.9 to be in the nutrition label is a nutrient content claim “[i]f such information is declared *elsewhere on the label* or in labeling,” and such claims are “subject to the requirements for nutrient content claims.” 21 C.F.R. § 101.13(c) (emphasis added); *see also Reid v. Johnson & Johnson*, 780 F.3d 952, 960 (9th Cir. 2015) (holding that nutrient statement mirroring nutrition label was a nutrient content claim and subject to § 101.13). HBS cannot escape the requirements of § 101.13 because the front label is a restatement of the information in the Supplemental Facts label. The front-label

claim “25G Protein Per Serving” meets the definition of an “expressed nutrient content claim” and is subject to the heightened requirements of 21 C.F.R. § 101.9(c)(7).

B. 12-Sample Testing is Not Required at the Pleading Stage

HBS next argues that even if the PDCAAS test is required for HexaPro, Plaintiffs’ claims still fail because they do not allege that they themselves conducted the PDCAAS test or a test of 12 samples “taken 1 from each of 12 different randomly chosen shipping cases” in compliance with 21 C.F.R. § 101.9(g)(2).⁴ In support HBS cites to several district court opinions that have dismissed similar claims based on this argument. *See Mee v. I A Nutrition, Inc.*, No. C-14-5006 MMC, 2015 WL 2251303, at *3–4 (N.D. Cal. May 13, 2015) (holding that a complaint supported by testing that is not compliant with § 101.9(g) is preempted); *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304, 1313 (E.D. Cal. 2014) (holding that because plaintiff failed to allege conducting a 12-sample test, her state law claims were preempted); *Vital v. One World Co.*, No. SACV 12-00314-CJC(MLGx), 2012 U.S. Dist. LEXIS 186203, *12–18 (C.D. Cal. Nov. 30, 2012) (dismissing lawsuit because plaintiff failed to present evidence regarding the 12-sample method after converting to a motion for summary judgment and allowing 45 days for plaintiff to conduct discovery).

Plaintiffs implicitly concede having not conducted a 12-sample test but point out courts have not required testing compliant with § 101.9(g)(2) at the pleading stage. *See Smith v. Allmax Nutrition, Inc.*, No. 1:15-CV-00744-SAB, 2015 WL 9434768, at *7–8 (E.D. Cal. Dec. 24, 2015) (allowing mislabeling claim to proceed where plaintiffs only pleaded conducting testing on a

⁴ Section 101.9(g) states that compliance with § 101.9 “shall be determined” by conducting a 12-sample test. 21 C.F.R. § 109(g). The 12-sample test involves choosing one subsample for each of 12 different “randomly chosen shipping cases, to be representative of a lot” and testing those subsamples in accordance with the method described in § 101.9(c). 21 C.F.R. § 101.9(g)(2). A lot is defined as a “[a] collection of . . . units of the same size, type, and style produced under condition as nearly uniform as possible . . .” 21 C.F.R. § 101.9(g)(1).

single sample); *see also Clay v. Cytosport, Inc.*, No. 15-CV-165 L DHB, 2015 WL 5007884, at *3 (S.D. Cal. Aug. 19, 2015) (plaintiff alleged sufficient facts to survive a motion to dismiss even though the sample was not tested with the methodology described in § 101.9(g)). The court in *Smith* summarized its reasoning, holding:

Rule 8 requires a plaintiff to state sufficient factual detail to allow the Court to reasonably infer that each named defendant is liable for the misconduct alleged. Based upon the allegations in the complaint, the Court can plausibly infer that tests conducted in compliance with the 12 sample methodology would support Plaintiff's allegations that the Product is mislabeled.

Smith, 2015 WL 9434768, at *7 (internal citations omitted).

In a case, filed by the same Plaintiffs as here and remarkably similar to this one, the court agreed with the reasoning in *Smith* and *Cytosport* when addressing this same question:

“[p]laintiff may rely on the testing results attached to the amended complaint to nudge his claims based on an overstated declaration of protein content ‘across the line from conceivable to plausible.’” *Gubala v. CVS Pharmacy, Inc.*, No. 14 C 9039, 2016 WL 1019794, at *8 (N.D. Ill. Mar. 15, 2016) (quoting *Twombly*, 550 U.S. at 570). Furthermore, the court held that whether testing compliant with § 101.9(g)(2) shows that the defendant overstated the protein content in the product “is an issue of proof, and Plaintiff does not need to prove his case at the pleadings stage of the case.” *Id.* This Court agrees. Plaintiffs are not required to plead compliance with § 101.9(g)(2) in order to survive a motion to dismiss, and their allegations, bolstered by the third-party testing results attached to the SAC, plausibly claim that the protein content claim on the front label would not be supported by the results of a PDCAAS test. The SAC is not preempted on these grounds.⁵

⁵ At this time the Court is not ruling on whether Plaintiffs are ultimately required to conduct testing compliant with § 101.9(g)(2) in order to prevail. The parties have not had the opportunity to fully brief that issue and it is most properly addressed, if at all, at a later stage.

C. Addition of BCAAs L-Leucine, L-Isoleucine, and L-Valine

Plaintiffs also allege that HexaPro does not include the BCAAs L-Leucine, L-Isoleucine, and L-Valine and thus its label is false and misleading in violation of 21 C.F.R. §§ 101.4(a)(1) and (b)(2)(i)–(ii). HBS again argues that Plaintiffs do not allege having conducted testing compliant with § 101.9(g)(2) demonstrating the absence of the BCAAs in question, so federal law preempts this claim. The contours of HBS’ argument on this issue are, for purposes of reviewing this motion, identical to HBS’ argument regarding preemption of the protein content claims. Plaintiffs allege that HBS does not in fact add the BCAAs to HexaPro and attach test results supporting this allegation. Therefore Plaintiffs have adequately pleaded a claim with respect to the addition of BCAAs, and, for the same reasons discussed above, that claim is not preempted for failing to allege compliance with § 101.9(g)(2) and survives HBS’ motion to dismiss.⁶

II. Addition of Alleged “Spiking” Amino Acids L-Glycine and L-Taurine

Next, HBS moves to dismiss Plaintiffs’ claim that HBS improperly fills HexaPro with the amino acids L-Glycine and L-Taurine arguing Plaintiffs do not allege a factually plausible basis that L-Glycine and L-Taurine do not improve the biological quality of the total protein in HexaPro. Plaintiffs allege that HBS adds L-Glycine and L-Taurine to artificially raise HexaPro’s protein content measurement and that these amino acids “do absolutely nothing to improve the biological quality of the total protein in [HexaPro]” in violation of 21 C.F.R. § 172.320. Doc. 52 ¶ 33. Section 172.320 regulates the addition of listed amino acids to food products. It permits the addition of amino acids if they are “used or intended for use to significantly improve the

⁶ The Court similarly is not ruling at this time on whether Plaintiffs are ultimately required to conduct § 101.9(g)(2) testing in order to prevail on their BCAA based claim.

biological quality of the total protein in a food containing naturally occurring intact protein.” 21 C.F.R. § 172.320(c).

Plaintiffs’ allegations regarding the addition of L-Glycine and L-Taurine are limited to four paragraphs which essentially restate 21 C.F.R. § 172.320 and claim, with no accompanying factual support, that L-Glycine and L-Taurine “do absolutely nothing to improve the biological quality of the total protein” in HexaPro. Doc 52 ¶¶ 32–35. In their opposition to the motion to dismiss, Plaintiffs argue that, supported by citations to two scientific articles, they allege that “[f]ree form amino acids are not absorbed as effectively as whole proteins, and their consumption does not produce the same health benefits as consuming whole proteins.”⁷ Doc. 52 ¶ 21.

This additional allegation does not bolster the claim as it does not in any way support the statement that “L-Glycine and L-Taurine do absolutely nothing to improve the biological quality of the total protein in [HexaPro].” Doc. 52 ¶ 33. Improving the biological content of the protein in a product at issue is the standard under § 172.320. Whether the amino acids are absorbed as effectively as whole protein is not relevant even if true, nor does the statement that “consumption [of free-form amino acids] does not produce the same health benefits as consuming whole proteins,” speak to the potential benefits or lack of benefits of consuming free-form amino acids in conjunction with whole proteins, which is the question § 172.320 requires the Court to examine to determine if a violation occurred. 21 C.F.R. § 172.320

In order to survive a motion to dismiss, a plaintiff “does not need detailed factual allegations,” however, the claim must be supported by “more than labels and conclusions, and a

⁷ HBS attached the cited portions of the articles to its reply brief and requests the Court take notice of the contents of the articles in ruling on the motion to dismiss. However, because the Court dismisses this claim on other grounds, it is unnecessary at this time to take notice of these documents.

formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (citations omitted). Plaintiffs have failed to allege any facts beyond bare conclusions of law that L-Glycine and L-Taurine do not improve the biological quality of the total protein in HexaPro and their claim that the product violates § 172.320 is dismissed without prejudice for failure to state a claim.⁸

III. Unjust Enrichment Claim

Plaintiffs’ unjust enrichment claim is premised on the same allegations as those underlying their consumer fraud claims—that HBS’ products are misleadingly labeled. Where “an unjust enrichment claim rests on the same improper conduct alleged in another claim, then the . . . unjust enrichment [claim] will stand or fall with the related claim.” *Cleary v. Phillip Morris Inc.*, 656 F.3d 511, 517–18 (7th Cir. 2011). For the reasons previously stated, the Court finds that Plaintiffs’ consumer fraud claims, with the exception of their claims founded on the addition of L-Glycine and L-Taurine, survive dismissal. Therefore, Plaintiffs’ unjust enrichment claim survives to the same extent as well.

IV. Express Warranty Claims

Finally, Plaintiffs assert a breach of express warranty claim against HBS alleging that HexaPro’s “labeling, marketing and advertising created express warranties as to [HexaPro’s] protein and BCAA content” and formed the “basis of the bargain.” Doc. 52 ¶ 88. HBS argues that Plaintiffs’ claim is “fatally vague” and has not corrected the deficiencies identified by this Court when it previously dismissed this claim. HBS further argues that even if Plaintiffs have stated a claim for breach of express warranty, such claim is preempted. The Court disagrees.

⁸ Though neither party raised this issue in its briefing, the Court notes that 21 C.F.R. § 172.320 does not appear to apply to the addition of L-Taurine to products because it is not listed in subsection (a).

To state a claim for breach of express warranty Plaintiffs must allege: “(1) an affirmation of fact or promise made to plaintiff; (2) relating to the goods; (3) which becomes part of the basis for the bargain; and (4) guaranteeing that the goods will conform to the affirmation or promise.” *Gubala*, 2016 WL 1019794, at *18 (quoting *Int’l Bhd. of Teamsters Local 734 Health & Welfare Trust Fund v. Phillip Morris, Inc.*, 34 F. Supp. 2d 656, 664 (N.D. Ill. 1998)). These elements of a breach of express warranty claim may be satisfied by attaching the alleged warranty to the complaint. *See Indus. Hard Chrome, Ltd. v. Hetran, Inc.*, 64 F. Supp. 2d 741, 747 (N.D. Ill. 1999) (allowing claim for breach of express warranty to proceed where plaintiffs attached the alleged warranty to the complaint).

In the First Amended Complaint Plaintiffs’ express warranty claim was premised on arguments that the label misrepresented the quality of the protein included in HexaPro by stating that it is made of “ultra-premium” protein and that the label misrepresented HexaPro as including only ultra-premium protein blend. The Court held that the statement regarding the quality of the protein in HexaPro is mere puffery or opinion language, and not a warranty, and that the claims regarding the ingredients were preempted because Plaintiffs had failed to allege a violation of the FDCA. Doc. 49 at 16. Plaintiffs restructure their express warranty claim in the SAC by focusing instead on the representations that HexaPro contains 25 grams of protein per serving and includes added BCAAs. Plaintiffs attach images of HexaPro’s front and back label in the SAC and allege that they relied upon the representations on the label that HexaPro contains 25 grams of protein per serving and BCAAs when deciding to purchase it. These restyled allegations avoid the deficiencies found in the First Amended Complaint as they relate to alleged misstatements of fact, not marketing language or puffery. Furthermore, as discussed in Section II above, Plaintiffs plausibly allege that the claims that HexaPro contains 25 grams of protein and

BCAAs violated the FDCA. *See Gubala v. CVS Pharmacy, Inc.*, 2016 WL 1019794, at *18 (allowing a breach of warranty claim to proceed where plaintiffs had adequately pleaded related violations of the FDCA). Having provided a statement of the content of the alleged warranty, Plaintiffs have sufficiently placed HBS on notice of the claim being brought, and these claims are not preempted. *See generally Ackerman v Coca-Cola, Inc.*, No. CV-09-0395, 2010 WL 2925955, at *7 (E.D.N.Y. July 21, 2010) (“[B]reach of warranty claims are generally not preempted because they are not requirements imposed under State law, but rather imposed by the warrantor”).

CONCLUSION

For the above stated reasons, HBS’ motion to dismiss [53] is granted in part and denied in part. The Court dismisses Plaintiffs’ claims, to the extent that they are premised on the violation of 21 C.F.R. § 172.320 for use of L-Taurine and L-Glycine, without prejudice. HBS is ordered to answer the remaining allegations of the Second Amended Complaint by May 18, 2016

Dated: May 4, 2016

A handwritten signature in black ink, appearing to read 'S. L. Ellis', written over a horizontal line.

SARA L. ELLIS
United States District Judge